K112377

MAR 2 3 2012

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: _____.

Submitter:

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- **Date Prepared:**

July 26, 2011

Name of the device:

- **Trade/Proprietary Name:** BS-400 Chemistry Analyzer, CLC 720 Chemistry Analyzer
  (BS-400 and CLC 720 are the same analyzers except the Models. For convenience of explanation, the BS-400 Chemistry Analyzer is represented of the two in this summary.)

- **Common Name:** Clinical Chemistry Analyzer (with optional ISE Module)

- **Classification Number/Class:**
  75JJE, Class I
  75CRF, Class II
  75CEM, Class II

75CGE, Class II
75JGS, Class II

Legally Marketed Predicate Device:

K904219 SYNCHRON CX7, BECKMAN
K072018 BS-200 Chemistry Analyzer, Mindray
K970664 GLUCOSE REAGENT, DERMA MEDIA LAB., INC.

Description:

The BS-400/CLC 720 Chemistry Analyzer is an automated clinical chemistry analyzer capable of performing various in vitro photometric assays. The Glucose was cleared under K970664 and is the chosen assay to demonstrate performance for the photometric unit. The BS-400 Chemistry Analyzer has an optional Ion-Selective Electrode (ISE) module which measures the concentration of the electrolytes, sodium, potassium, and chloride, in samples using ion selective electrode technology.

Intended Use:

The BS-400 Chemistry Analyzer is an automated chemistry analyzer for in vitro diagnostic use in clinical laboratories. The analyzer is designed for the in vitro quantitative determination of clinical chemistries in serum, plasma, urine or cerebral spinal fluid samples.

Comparison of Technological Characteristics:

Substantial equivalence has been demonstrated between the BS-400 Chemistry Analyzer and SYNCHRON CX7 analyzer. Both of them utilize absorbance photometry to perform and output quantitative results for kinetic and endpoint clinical chemistries. For analytes, the BS-400 Chemistry Analyzer and SYNCHRON CX7 analyzer determine the concentration of unknown samples from a standard curve generated with known analyte concentrations. The BS-400 Chemistry Analyzer and BS-200 Chemistry Analyzer both utilize Ion-Selective Electrodes technology and are equipped with the same ISE Module.

Performance Characteristics:

Performance testing of the BS-400 Chemistry Analyzer consisted of running the FDA previously cleared assay and the ISE module on the BS-400 to evaluate precision, linearity, and method comparison, Limits of Detection and Limits of Quantitation, interference.

A correlation analysis between the BS-400 Chemistry Analyzer and the predicate devices yielded

the following results:

Item	Regression slope	Regression intercept	Correlation coefficient square R^2	Sample numbers
GLU（mg/dL）	0.989	1.31	0.999	218
Serum K^+ (mmol/L) (ISE)	1.0139	0.0384	0.9973	40
Serum Na^+ (mmol/L) (ISE)	1.0101	-0.9322	0.9975	40
Serum Cl^- (mmol/L) (ISE)	0.9837	0.5059	0.9957	40
Urine K^+ (mmol/L) (ISE)	0.9671	2.1934	0.9996	40
Urine Na^+ (mmol/L) (ISE)	1.0256	-13.841	0.9994	40
Urine Cl^- (mmol/L) (ISE)	0.9981	2.4059	0.9996	40

Precision of Glucose test yielded the following results:

Specimen			Within Run		Total	
Sample	n	mean	SD	%CV	SD	%CV
Serum						
Control 1	120	56.3	0.57	1.0%	0.88	1.6%
Pool 1	120	117.0	0.83	0.7%	1.74	1.5%
Control 2	120	561.6	3.42	0.6%	6.84	1.2%
Urine						
Pool 1	117	14.9	0.26	1.7%	0.32	2.1%
Pool 2	117	194.3	1.08	0.6%	1.91	1.0%
Pool 3	120	330.0	1.80	0.5%	2.95	0.9%

The Within-Run precision of ISE module test yielded the following results:

Item	Level I			Level II		
	Mean	SD	CV%	Mean	SD	CV%
K serum(ISE)	3.49	0.02	0.54%	6.21	0.03	0.43%
Na serum(ISE)	128.1	0.63	0.49%	150.8	0.50	0.33%
CL serum(ISE)	84.8	0.95	1.12%	117.9	0.51	0.44%
K Urine(ISE)	21	0.51	2.48%	44	0.00	0.00%
Na Urine(ISE)	65	1.60	2.46%	124	1.81	1.47%
CL Urine(ISE)	53	1.08	2.03%	106	1.15	1.08%

The Between-run imprecision of ISE module test yielded the following results:

Item	Level I			Level II		
	Mean	SD	CV%	Mean	SD	CV%
K (mmol/L) serum(ISE)	3.48	0.03	0.78%	6.17	0.04	0.64%
Na (mmol/L) serum(ISE)	129.1	1.00	0.78%	150.4	0.89	0.59%
CL (mmol/L) serum(ISE)	85.1	1.10	1.29%	117.1	0.96	0.82%
K (mmol/L) Urine(ISE)	21	0.47	2.23%	44	0.24	0.56%
Na (mmol/L) Urine(ISE)	67	3.19	4.75%	126	3.45	2.74%
CL (mmol/L) Urine(ISE)	56	2.13	3.83%	108	2.02	1.87%

The linearity test yielded the following results:

Item	Linear range	
	Lower limit	Upper limit
GLU (mg/dL) (Specimen :Serum/Plasma)	5	700
GLU (mg/dL) (Specimen :Urine)	2	700

K (mmol/L) serum(ISE)	0.94	8.18
Na (mmol/L) serum(ISE)	71.00	232.28
CL (mmol/L) serum(ISE)	49.60	198.18
K (mmol/L)Urine(ISE)	3.50	209.25
Na (mmol/L) Urine(ISE)	9.25	725.50
CL (mmol/L)Urine(ISE)	7.25	693.25

The Limit of Detection test yielded the following results:

Item	LoB	LoD	LoQ
GLU（mg/dL）(Specimen :Serum)	2.2	2.6	/
GLU（mg/dL）(Specimen :Urine)	0.6	0.9	/
K (mmol/L) serum(ISE)	0.07	0.10	0.52
Na (mmol/L) serum(ISE)	1.28	2.06	4.38
CL (mmol/L) serum(ISE)	2.30	3.56	5.12
K (mmol/L)Urine(ISE)	1.50	2.42	3.70
Na (mmol/L) Urine(ISE)	5.50	8.98	10.98
CL (mmol/L)Urine(ISE)	3.50	5.91	7.15

The Interference of Glucose test yielded the following results:

Effects of icterus, hemolysis, and lipemia are shown by spiking serum pools with bilirubin, hemoglobin, and Intralipid® 20% emulsion. Other substances are also tested. Interference is defined as a shift in results by more than both 3 mg/dL and 3%.

Interferent	Glucose Concentration	Interferent Concentration	Observed Interference
Ascorbic acid	76 mg/dL 140 mg/dL	30 mg/L	none
Bilirubin	78 mg/dL 138 mg/dL	5.4 mg/dL 9.8 mg/dL	-3%* -3%*
Hemoglobin	74 mg/dL 134 mg/dL	400 mg/dL	none
Lipemia (from Intralipid®)	72 mg/dL 139 mg/dL	400 mg/dL 67 mg/dL	+ 3.1 mg/dL + 3%*

Metronidazole	75 mg/dL 137 mg/dL	27 mg/L 35 mg/L	+ 3 mg/dL* + 3%*
Tetracycline	76 mg/dL 140 mg/dL	15 mg/L	none
EDTA	76 mg/dL 145 mg/dL	8 mg/mL	none
Potassium oxalate	76 mg/dL 146 mg/dL	8 mg/dL	none
Sodium citrate	76 mg/dL 145 mg/dL	140 mg/dL	none
Sodium fluoride	77 mg/dL 145 mg/dL	10 mg/dL	none

*Amount of interference is interpolated from the results of adjacent spiked samples.

The Interference of ISE module test yielded the following results:

Item	Interference materials		
	Hemoglobin	Bilirubin	Lipemia Intralipids®
Serum K^+ (mmol/L)	>500 mg/dL	>40 mg/dL	>1000 mg/dL
Serum Na^+ (mmol/L)	>500 mg/dL	>40 mg/dL	>1000 mg/dL
Serum Cl^- (mmol/L)	>500 mg/dL	>40 mg/dL	>1000 mg/dL

Conclusion:

The data demonstrates that the BS-400 Chemistry Analyzer is substantially equivalent to SYNCHRON CX7 Analyzer and BS-200 Chemistry Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Shenzhen Mindray Bio-Medical Electronics Co., Ltd
c/o Susan D. Goldstein-Falk
MDI Consultants, Inc
55 Northern Blvd., Suite 200
Great Neck, NY 11021

MAR 2 3 2012

Re: k112377
Trade/Device Name: BS-400/CLC 720 Chemistry Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CFR, JGS, CEM, CGZ, JJE
Dated: March 9, 2012
Received: March 12, 2012

Dear Ms. Goldstein-Falk,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k112377

Device Name: BS-400/CLC 720 Chemistry Analyzer

Indications For Use:

The BS-400/CLC 720 Chemistry Analyzers are designed for clinical laboratory use, making direct quantitative measurements of Na+ (sodium), K+ (potassium), Cl- (chloride) in serum, plasma and urine samples and Glucose in serum samples plasma and urine samples. Additionally, other various chemistry assays may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.

Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K112377